

DETAILED ACTION

Claim Objections

1. Claims 1-11 are objected to because of the following informalities: It is suggested that the Applicant amend the claims as follows in order to provide positive method steps in claims 1 and 3, and definitive structural elements in claims 7-9 and 11. Appropriate correction is required.

It is suggested that Claim 1 be amended to read:

1. A blood sugar level measuring method for measuring blood sugar level, the method comprising:

providing [using] a measuring apparatus comprising a body-surface contact portion, a temperature detecting portion for measuring temperatures on the body surface and of the environment, and an optical measuring portion for measuring the hemoglobin concentration and hemoglobin oxygen saturation in blood, wherein blood sugar level is calculated based on measurement data provided by said temperature detecting portion and by said optical measurement portion, [said method comprising:]

a first step of determining whether or not the output from said temperature detecting portion is within a predetermined range when the body surface is not in contact with said body-surface contact portion; and

a second step of continuing with measurement if said output is within the predetermined range but making an error display and resetting the measurement if said output is outside the predetermined range.

It is suggested that Claim 3 be amended to read:

3. A blood sugar level measuring method for measuring blood sugar level, the method comprising:

providing [using] a measuring apparatus comprising a body-surface contact portion, a temperature detecting portion for measuring temperatures on the body surface, and an optical measuring portion for measuring the hemoglobin concentration and hemoglobin oxygen saturation in blood, wherein blood sugar level is calculated based on measurement data provided by said temperature detecting portion and by said optical measurement portion, [said method comprising:]

a step of detecting chronological change in the output from said temperature detecting portion;

detecting the presence or absence of contact of a body surface to said body-surface contact portion based on the chronological change in said output;

a first step of starting the storage of said measurement data for the calculation of said blood sugar level upon detection of contact of the body surface to said body surface contact portion;

a second step of detecting the moment of departure of the body surface from said body surface contact portion based on chronological changes in the output from said temperature detecting portion; and

a third step of making an error display and resetting the measurement if the detected moment is within a predetermined time, or if the departure of the body surface from said body surface contact portion is not detected a certain time after said predetermined time.

Claim 7, line 13 should be amended to include the phrase - - is configured to determine - - after the term "portion", and to delete the term "determines" before the term "whether"; Claim 7, line 15 should be amended to include the phrase - - is configured to cause - - after the term "portion", and to delete the term "causes" before the term "said"; Claim 8, line 2 should be amended to include the phrase - - is configured to identify - - after the term "portion", and to

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delete the term “portions” before the phrase “the moment”; Claim 9, line 2 should be amended to include the phrase - - is configured to instruct - - after the term “portion”, and to delete the term “instructs” before the phrase “an error display”; Claim 11, line 2 should be amended to include the phrase - - is configured to determine - - after the term “portion”, and to delete the term “determines” before the term “whether”.

Double Patenting

2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Claim 7 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 12 of U.S. Patent No. 7,215,983. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claim of the US Patent discloses all the elements of the current invention except for a control portion that causes a calculation portion to calculate blood sugar if an error decision portion determines that the temperature of the body surface and of the environment are within a predetermined range, as set forth in the claims. However, it was well known in the art at the time of the invention to proceed with a measurement if a system check measurement falls within a predetermined range. It would have been obvious to one of ordinary skill in

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the art at the time of the invention to include a control portion for causing a blood sugar level calculation to proceed if the temperature on the body surface and the temperature of the environment are within a predetermined range.

Allowable Subject Matter

4. The following is an examiner's statement of reasons for allowance: Applicant cites several references related to the measurement of analyte concentrations. Oosta et al.'480 (cited by Applicant) teaches the use of temperature measurements to calibrate an optical glucose measurement based upon the skin type of a subject. Cho'414 (cited by Applicant) teaches determining glucose concentrations based upon temperature analysis and spectral measurements. Iitawaki et al.'314 (cited by Applicant) teaches a measurement portion for obtaining a plurality of measurement values and a calculation portion for calculating a blood sugar level based on the plurality of measured values, wherein one of the values is related to a heat measurement. Cho et al.'996 (USPN 5,924,996) teaches a measuring portion for measuring blood sugar levels based on heat radiating from the skin of a user and a temperature of the environment. However, none of the prior art teaches or suggests, either alone or in combination, a method or apparatus wherein a blood sugar level is calculated based on measurement data provided by a temperature detecting portion that measures a plurality of temperatures on the body surface and of the environment, and from an optical measurement portion that measures hemoglobin concentration and hemoglobin oxygen saturation in blood, in combination with the other claimed steps or elements.

5. Claims 1-6 would be allowable if rewritten to overcome the objection set forth in paragraph 1 above.

6. Claims 8-11 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims, and to overcome the objections set forth in paragraph 1 above.

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Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ETSUB D. BERHANU whose telephone number is (571)272-6563. The examiner can normally be reached on Monday - Friday (7:00 - 3:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on (571)272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Eric F Winakur/
Primary Examiner, Art Unit 3768

EDB